PATENT

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Date: April 2, 1999
File No.: 3216/75036

Sir:

Transmitted herewith for filing is the patent application

Inventor(s): **Hechel, et al.**

For: **THERMAL FILM ULTRASONIC DOSE INDICATOR**

I hereby certify that this paper is being deposited with the United States Postal Service as Express Mail in an envelope addressed to: ASSISTANT COMMISSIONER FOR PATENTS, Washington, D.C. 20231, on this date.

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Enclosed are:

(X) **12** pages of specification, including **17** claims and an abstract.

( ) An executed oath or declarations, with power of attorney.

(X) An unexecuted oath or declaration, with power of attorney.

(X) **3** sheet(s) of informal drawing(s).

( ) ____ sheet(s) of formal drawings(s).

( ) An Assignment of the invention to _____.

( ) Assignment Form Cover Sheet.

( ) A check in the amount of $_____ to cover the fee for recording the assignment(s) is enclosed.

( ) Associate power of attorney.

Fee Calculation For Claims As Filed

a)	Basic Fee							$760.00
b)	Independent Claims	4	- 3 =	1	x	$ 78.00	=	$ 78.00
c)	Total Claims	17	- 20 =	0	x	$ 18.00	=	$_____
d)	Multiple Dependent Claims					$260.00	=	$ 0
						Total Filing Fee		$838.00

(X) **1** unexecuted Statement of Status as Small Entity, reducing Filing Fee by half to $419.00

( ) A check in the amount of $_____ to cover the filing fee is enclosed.

( ) Charge $____ to Deposit Account No. _____.

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( ) The Commissioner is hereby authorized to charge any additional fees which may be required to this application under 37 C.F.R. §§1.16-1.17, or credit any overpayment, to Deposit Account No. _____. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. _____. Two duplicate copies of this sheet are enclosed.

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Registration No. 34,137

ADM049/1095

Applicant or Patentee: Hechel et al Atty Docket No. 3216/75036
Serial or Patent No.: _____
Filed or Issued: _____
For: THERMAL FILM ULTRASONIC DOSE INDICATOR

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS

(37 CFR 1.9(f) AND 1.27(c) - SMALL BUSINESS CONCERN)

I hereby declare that I am

( ) the owner of the small business concern identified below:
(X) an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN: FibraSonics Inc.
ADDRESS OF CONCERN: 5312 N. Elston Avenue, Chicago, IL 60630

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.12, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees to the United States Patent and Trademark Office, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time, or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled:

THERMAL FILM ULTRASONIC DOSE INDICATOR

by inventor(s): Hechel et al.
described in:

(X) the specification filed herewith.
( ) application serial no. _____, filed _____.
( ) Patent No. _____, issued _____.

If the rights held by the above-identified small business concern are not exclusive, each individual, concern, or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d), or a nonprofit organization under 37 CFR 1.9(e).
*NOTE: Separate verified statements are required from each named person, concern, or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

NAME _____
ADDRESS _____
( ) INDIVIDUAL( ) SMALL BUSINESS CONCERN ( ) NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING: Mary Anne Kirchschlager
TITLE OF PERSON OTHER THAN OWNER: Secretary/Treasurer
ADDRESS OF PERSON SIGNING: 5312 N. Elston Avenue, Chicago, IL 60630
SIGNATURE: _____ Date: _____

THERMAL FILM ULTRASONIC DOSE INDICATOR

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to ultrasound and more particularly to ultrasound devices used for imaging, cutting or removal of tissue and/or matter from a living body.

2. Description of Related Art

Probes or scalpels for the fragmentation and removal of materials, tissue and fluids from living beings are known to the art. For example, U.S. Pat. No. 2,227,727, issued Jan. 7, 1941 to Vincent Leggiardro, discloses an apparatus for fragmenting naturally formed stones, such as kidney stones, and the like, utilizing a high speed reciprocating rod which may have a blunt end, a sharp or chisel point, a cutting blade, or combination thereof, such as a cutting blade having a blunt end.

A particular arrangement in an ultrasonically vibrated surgical tool using an irrigation fluid and an anti-coagulant is disclosed in U.S. Pat. No. 4,493,694, issued Jan. 15, 1985, to David G. Wuchinich, utilizes a hollow tool having a suction passage and at least one pre-aspirating orifice in the wall of the tool, and a plastic sleeve concentrically spaced about the tool for admitting fluid from a supply into the space between the tool and passing substantially all of the fluid through the pre-aspirating orifice.

In the application of ultrasonics to liposuction, instruments of varying configurations recently have been proposed. In U.S. Pat. No. 5,236,414, issued Aug. 17,

1993 to Katsuya Takasu, a tubular body defining a suction passage has an opening in its front lower end, and an outer tube having a corresponding opening, by means of which fat tissue is crushed and/or emulsified due to the vibration of the front end of the tubular body and is then aspirated. In U.S. Pat. No. 5,514,086, issued May 7, 1996, to Parisi et al., an ultrasonically vibrated hollow probe has a port in its surface for aspiration and a tip substantially formed of plastic.

While the use of ultrasound has proven effective, its use must be carefully controlled. For example, external ultrasonic power is often used in order to ease the internal lipoplasty operation by breaking down the membranes of fat cells. A surgeon performing such a procedure has no feedback on how much energy is delivered over any given time span within a given area of treatment. Ultrasonic cutting and fragmentation tools suffer from the same limitation. Because of the importance of ultrasound treatments, a need exists for a method of measuring and controlling the energy delivered during the ultrasound treatment.

3. Summary

A method and apparatus are provided for applying an ultrasound treatment to a portion of a human body. The method includes the steps of determining a temperature rise which the body portion will experience when a dosage limit of the ultrasound treatment has been reached. The method further includes the steps of disposing on the body portion an indicator adapted to provide a visual change at the determined temperature and applying ultrasound to the body portion until the indicator provides the visual change at the determined temperature.

4. Brief Description of the Drawings

FIG. 1 depicts a system for applying ultrasound in accordance with an embodiment of the invention;

FIG. 2 is a graph of the heating effects of ultrasound that may be used with the system of FIG. 1; and

FIG. 3 depicts temperature indicators that may be used by the system of FIG. 1.

5. Detailed Description of an Illustrated Embodiment

FIG. 1 depicts an ultrasonic system 10, generally, in accordance with an illustrated embodiment of the invention. The ultrasonic system 10 generally includes an ultrasonic power source 12, a transducer 14, a connector cable 16 and one or more thermal detectors 20.

Under the illustrated embodiment, an ultrasonic source (e.g., a generator) 12 generates a controlling electrical signal which is applied, through an attachment cable 16 to an ultrasonic transducer 14. The transducer 14 converts the electric signal into an ultrasound signal, which may then propagate into a portion 18 of a living human body.

The ultrasonic transducer 14 may be mechanically coupled to a probe for ultrasonic cutting or liposuction. In the alternative, the transducer 14 may also be an ultrasonic transceiver used for imaging.

Under the illustrated embodiment, the application of ultrasonic energy to the portion 18 is accompanied by the user of thermal indicators 20. The thermal indicators 20 may be attached to an outer surface of the portion 18 and may be used to detect a localized temperature of the portion 18. The detection of the localized temperature has been found to be important in avoiding overuse of ultrasonic energy. Such detection has important

implications for both therapeutic and diagnostic ultrasound procedures.

The thermal indicators 20 may be a thermally reactive film (e.g., a thermochromatic film) fabricated to change color or opacity at a predetermined temperature. Such devices are well known and will not be discussed further, other than to note that the thermal indicators 20 differ from prior art devices (i.e., used with the human body) in that the indicators 20 are generally fabricated to provide a response only at a predetermined temperature above a normal body temperature.

The thermal indicators 20 may be fabricated of a thin plastic sandwich with a colored background layer which may be revealed only when the temperature of the portion 18 exceeds the calibrated temperature of the indicator 20. Further, alpha-numeric coding (e.g., "DOSAGE REACHED") may be printed on the background and may only be revealed when the portion 18 exceeds the calibrated temperature of the indicator 20.

The indicators 20 may be fabricated with an adhesive disposed on a rear surface, which allows the indicator 20 to be directly attached to the skin of a patient at nearly any location. The relatively thin nature of the indicator 20 allows the transducer 14 to be swept over the indicator 20 without interaction with the ultrasonic signal or interference with transmission of the ultrasonic signal into the portion 18.

The indicators 20 may be provided to a user on a plastic backing 24 (FIG. 3). A temperature calibration level of each indicator 20 may be color-coded onto a tab 26 of the indicators 20.

The indicators 20 may be disposable and may be provided in packs of 10 each, as shown in FIG. 3. Such

packs may be conveniently attached to an outside surface of the generator 12.

In use, the indicators 20 may be applied to the portion 18, as necessary. As dosage limits are reached (as noted by color change), the indicators 20 may be removed. A technician may then only focus on those areas of the portion 18 still containing indicators 20.

FIG. 2 is an example of an in-depth heat distribution plot that may be obtained using the system 10 of FIG. 1 operating at a particular ultrasound frequency. More specifically, FIG. 2 is a graph of tissue temperature (versus depth and time) of the portion 18 where the transducer 14 is operated at 1.0 MHz and a power level of approximately 3 Joules/cm^2.

It may be noted from FIG. 2, that the 1.0 MHz signal has an ultrasound penetration depth which results in a tissue temperature rise at a depth of approximately 2.5 cm. Heating produced at other depths may be obtained by using slightly different ultrasonic frequencies. It has been found that an ultrasonic dosage limit of the portion 18 can be correlated to an ultrasound penetration depth, a mass and thickness of the treated layer and to a surface temperature overlying the treated areas.

For instance, the ultrasound energy heats up the inner layers of tissue at the ultrasound penetration depth. These layers radiate heat to the neighboring layers. In the case of abdominal lipoplasty (where the patient lays on her back), the temperature gradient is directed upwards because of the added convective effect. The convective effect causes the superficial layer and surface to be heated up. The surface temperature has been found to represent the inner temperature rise indirectly.

To practice the procedure, a mass of a fat layer may be determined for a particular area to be treated. An ultrasound penetration depth may be selected using a frequency control 22 on the source 12 based upon the thickness and mass to be treated. Using a specific heat of the area and power output of the transducer 14, a rate of rise of temperature may be determined for a particular dosage limit. By knowing a distance from the surface where heat localization will occur, a predicted temperature at the surface may be determined for the dosage limit.

It has been found that uniformity of ultrasonic dosage level in Joules/cm^3 can be achieved by the expeditious use of the indicators 20. For example, in the case of pretreatment for liposuction (i.e., to facilitate fat dissociation) it has been found that indicators calibrated to 1 ^oC above a normal body temperature works well for detecting (and limiting) ultrasound dosage for layers of fat of an intermediate thickness (e.g., one inch). A higher calibration temperature (e.g., 1.25-1.5 ^oC) may be used for thicker layers. A lower level (e.g., 0.25 ^oC) may be used for thinner layers.

In the case where the portion 18 of FIG. 1 is the pelvis of a human subject undergoing liposuction, a profile may be obtained of a fat depth to be removed. The treatment may be tailored to the specific location on the exterior surface of the portion 18.

Since a fat layer in a pelvic area of a human subject varies by location (e.g., across the buttocks), the dosage level may also vary, as may the ultrasonic frequency. Further, the presence of bone in an area of an ultrasonic treatment may reflect ultrasonic energy and

provide a different temperature gradient across the fat layer.

To provide a measure of dosage, one or more temperature indicators 20 may be placed in the treatment area. The indicators 20 may be calibrated to a single temperature or a number of different indicators 20 may be used with each calibrated to a different temperature.

For example, for areas of intermediate fat thickness, an indicator 20 may be provided with a calibrated temperature value of 38 ^{o}C (e.g., 1 ^{o}C above a normal body temperature). Areas of thicker fat may be provided with a higher calibrated value (e.g., 39 ^{o}C). Areas of less fat may be provided with a lower calibrated value (e.g., 37.25 ^{o}C).

In the case of pretreatment for liposuction, fat cell dissociation may be accomplished by first placing one or more indicators 20 over the area to be treated. Following tumescent infusion, grid lines may be drawn on the patient, corresponding to the contour lines that may already have been drawn on the patient by the surgeon. The indicators 20 may be removed from a sterile pouch and individually placed at the centers of each of the grids. As the nurse moves the ultrasound applicator 14 over the grid, the indicators 20 will change color, upon reaching the appropriate temperature, and revealing the words "DOSE REACHED - REMOVE TAB". As the nurse removes each indicator and moves on to the next grid, the entire region maybe optimally dosed.

As an alternative to treating the grid spaces individually, the nurse may sweep the transducer 14 over the entire area to be treated. Where the areas treated include a continuum of thick and thin areas of fat, it would be expected that some indicators 20 would give indication of completion of treatment before other

indicators 20. In this case, the technician would continue to treat the areas of thicker fat until the indicators 20 associated with those areas also give indication of completion of treatment.

A specific embodiment of a method and apparatus for applying according to the present invention has been described for the purpose of illustrating the manner in which the invention is made and used. It should be understood that the implementation of other variations and modifications of the invention and its various aspects will be apparent to one skilled in the art, and that the invention is not limited by the specific embodiments described. Therefore, it is contemplated to cover the present invention any and all modifications, variations, or equivalents that fall within the true spirit and scope of the basic underlying principles disclosed and claimed herein.

6. Claims

1. Apparatus for applying an ultrasound treatment to a portion of a human body, such apparatus comprising:

means disposed on the portion for providing a visual indication when a dosage limit of the ultrasound treatment has been reached; and

means adapted to secure the means for indicating to the portion of the human body.

2. The apparatus for applying an ultrasound treatment as in claim 1 further comprising an ultrasonic source.

3. The apparatus for applying an ultrasound treatment as in claim 1 further comprising an ultrasonic transducer coupled to the ultrasonic source.

4. Apparatus for applying an ultrasound treatment to a portion of a human body, such apparatus comprising:

a thermochromic strip disposed on the portion for providing a visual indication when a dosage limit of the ultrasound treatment has been reached; and

means adapted to secure the thermalchromatic strip to the portion of the human body.

5. The apparatus for applying an ultrasound treatment as in claim 4 wherein the means for securing further comprise and adhesive disposed on a surface of the thermalchromatic strip.

6. The apparatus for applying an ultrasound treatment as in claim 4 further comprising an ultrasonic source.

7. The apparatus for applying an ultrasound treatment as in claim 4 further comprising an ultrasonic transducer coupled to the ultrasonic source.

8. A method of applying an ultrasound treatment to a portion of a human body, such method comprising the steps of:

determining a temperature rise which the body portion will experience when a dosage limit of the ultrasound treatment has been reached;

disposing on the body portion an indicator adapted to provide a visual change at the determined temperature;

applying ultrasound to the body portion until the indicator provides the visual change at the determined temperature.

9. The method of determining when a dosage limit has been reached as in claim 8 wherein the step of

determining a temperature rise further comprises determining an ultrasound penetration depth to be achieved for the body portion.

10. The method of determining when a dosage limit has been reached as in claim 8 wherein the step of determining an ultrasound penetration depth to be achieved for the body portion further comprises selecting a frequency of the ultrasound source to achieve the ultrasound penetration depth.

11. The method of determining when a dosage limit has been reached as in claim 8 wherein the step of selecting a frequency of the ultrasound heating source further comprises determining an average depth of penetration of the ultrasound for the selected frequency.

12. Apparatus for applying an ultrasound treatment to a portion of a human body, such apparatus comprising:

means disposed on the portion for providing a visual indication when a dosage limit of the ultrasound treatment has been reached;

means for applying ultrasound to the body portion until the means for providing indicates that the dosage limit has been reached.

13. The apparatus for applying as in claim 12 wherein the means for applying ultrasound further comprises means for controlling an ultrasound penetration depth to be achieved for the body portion.

14. The apparatus for applying as in claim 12 wherein the means for providing a visual indication further comprises a thermalchromatic strip.

15. The apparatus for applying as in claim 14 wherein the thermalchromatic strip further comprises a relatively thin plastic sandwich.

16. The apparatus for applying as in claim 15 wherein the plastic sandwich further comprises a colored background.

17. The apparatus for applying as in claim 15 wherein the colored background further comprises alpha-numeric characters.

7. Abstract

A method and apparatus are provided for applying an ultrasound treatment to a portion of a human body. The method includes the steps of determining a temperature rise which the body portion will experience when a dosage limit of the ultrasound treatment has been reached. The method further includes the steps of disposing on the body portion an indicator adapted to provide a visual change at the determined temperature and applying ultrasound to the body portion until the indicator provides the visual change at the determined temperature.

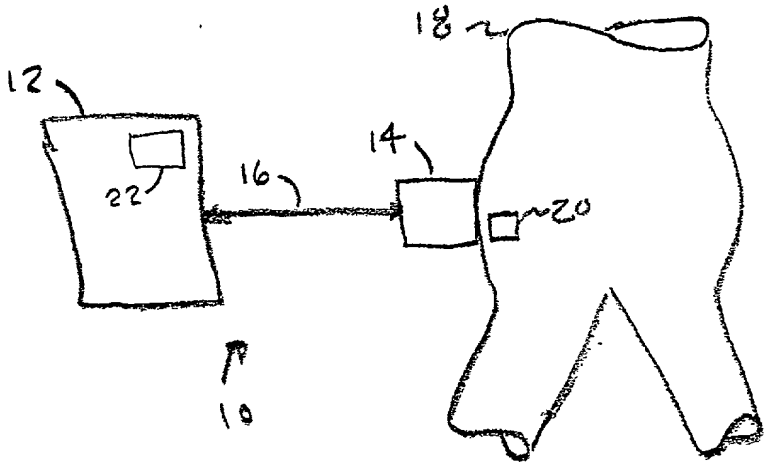
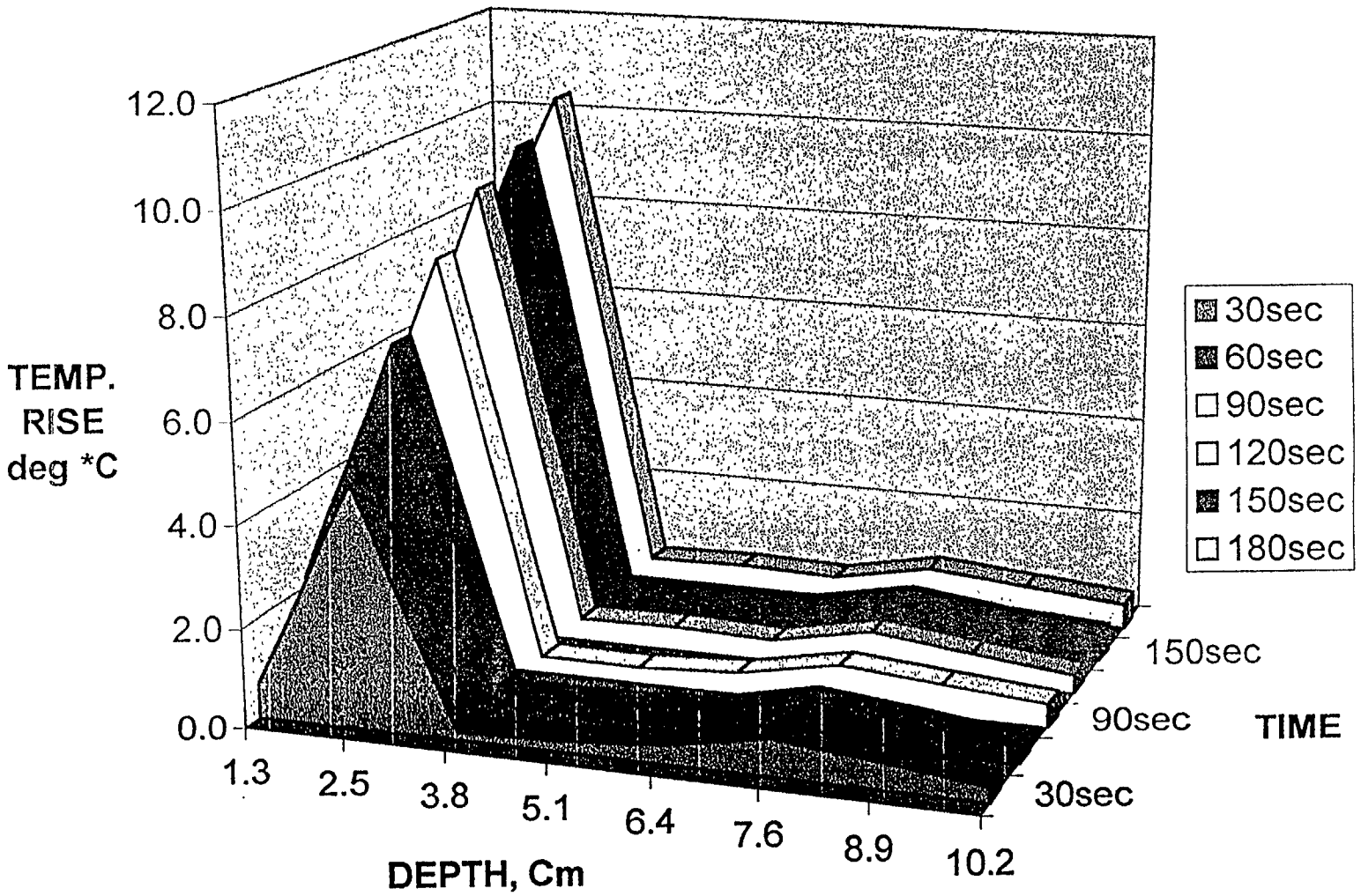


FIG. 1

Figure 2: IN-DEPTH HEAT DISTRIBUTION



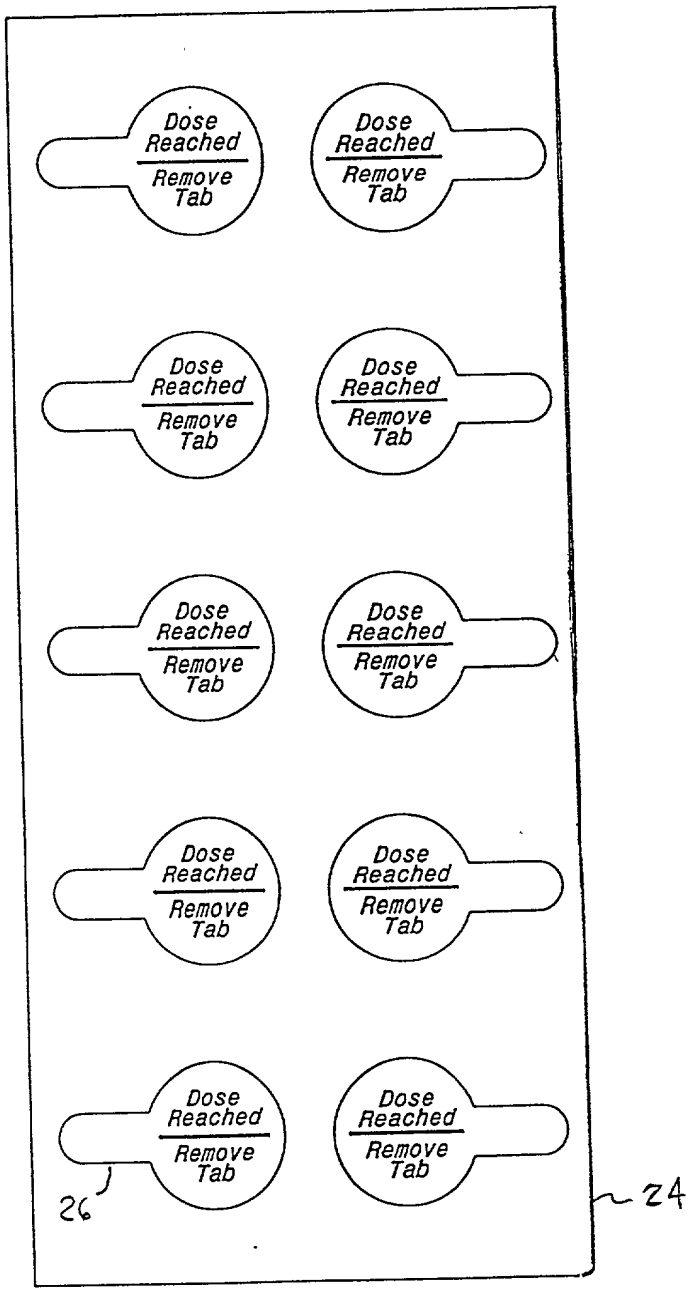

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FIG 3

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare:

That my residence, post office address and citizenship are as stated below next to my name.

That I verily believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a design patent is sought on the invention entitled:

THERMAL FILM ULTRASONIC DOSE INDICATOR

the specification of which (check one)
(X) is attached hereto.
( ) was filed on _____ as
Application Serial No. _____
and was amended on _____
(if applicable)

That I have reviewed and understand the contents of the above-identified specification, including the claim, as amended by any amendment referred to above.

That I acknowledge the duty to disclose information known to be material to patentability of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

That I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate on this invention having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)			Priority Claimed
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	Yes No
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	Yes No

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below.

_____ (Application Number) _____ (Filing Date)

_____ (Application Number) _____ (Filing Date)

That I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

United States Application(s)

_____ (Application Serial No.)	_____ (Filing Date)	_____ (Status)-(Patented, pending, abandoned)
_____ (Application Serial No.)	_____ (Filing Date)	_____ (Status)-(Patented, pending, abandoned)

That all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any design patent issuing thereon.

I hereby appoint the following attorneys, with full power of substitution and revocation, to prosecute this application and to transact all business in the United States Patent and Trademark Office connected therewith and request that all correspondence and telephone calls in respect to this application be directed to WELSH & KATZ, LTD., 120 South Riverside Plaza, 22nd Floor, Chicago, Illinois 60606, Telephone No. (312) 655-1500:

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Inventor's signature: _____

Date: _____

Residence and Post Office Address: _____

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